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ABSTRACT:

A urinary catheter (1) having a relatively narrow shaft (3) with a pointed distal end part (4) for introduction into the urethra and arrangement of the distal end part within the bladder, and a proximal end part formed by a terminal member (6) of larger cross-sectional dimensions than the shaft is accommodated in a catheter package (2) having walls of a flexible foil material. At a distal end part (2c) of the package, opposed local sections define a relatively narrow gateway (2d) allowing passage of said shaft (3), but forming a liquid seal when engaged by said terminal member (6). The distal end part as well as an opposite proximal end part (2a) are separable from an intermediate section (2b) of the package by local opening means (8, 9; 14, 15) permitting opening of the package.





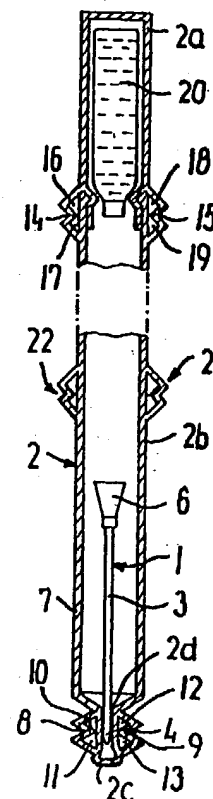
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<p>(21) International Application Number: PCT/DK98/00556</p> <p>(22) International Filing Date: 16 December 1998 (16.12.98)</p> <p>(30) Priority Data: 1473/97 17 December 1997 (17.12.97) DK</p> <p>(71) Applicant (for all designated States except US): COLOPLAST A/S [DK/DK]; Holtedam 1, DK-3050 Humleback (DK).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): TORSTENSEN, Jan [DK/DK]; Egeløvsvej 30, DK-2830 Virum (DK). NØSTED, Ulrik [DK/DK]; Willemoesgade 34, DK-2100 Copenhagen Ø (DK).</p> <p>(74) Agents: CARLSSON, Eva et al.; Internationalt Patent-Bureau, Høje Taastrup Boulevard 23, DK-2630 Taastrup (DK).</p>	<p>(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>	

(54) Title: A URINARY CATHETER ASSEMBLY READY FOR USE

## (57) Abstract

A urinary catheter (1) having a relatively narrow shaft (3) with a pointed distal end part (4) for introduction into the urethra and arrangement of the distal end part within the bladder, and a proximal end part formed by a terminal member (6) of larger cross-sectional dimensions than the shaft is accommodated in a catheter package (2) having walls of a flexible foil material. At a distal end part (2c) of the package, opposed local sections define a relatively narrow gateway (2d) allowing passage of said shaft (3), but forming a liquid seal when engaged by said terminal member (6). The distal end part as well as an opposite proximal end part (2a) are separable from an intermediate section (2b) of the package by local opening means (8, 9; 14, 15) permitting opening of the package.





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## A Urinary Catheter Assembly Ready for Use.

The present invention relates to a urinary catheter assembly comprising an elongate urinary catheter of a predetermined length and having a relatively narrow shaft with a pointed distal end part with one or more urine inlet openings for introduction into the urethra and arrangement of said distal end part within the bladder and a proximal end part formed by a terminal member of larger cross-sectional dimensions than said shaft, and an elongate catheter package defining a cavity for relatively narrow accommodation of said shaft.

Urinary catheters of this kind are increasingly used for so-called intermittent catheterization of the bladder. A typical use is for post-operative urine retention of newly operated patients in hospitals, for whom intermittent catheterization performed with intervals of 3 to 6 hours has brought a significantly reduced risk of infection of the urethra and the bladder compared to permanent catheterization.

Another typical use is with patients suffering from severe cases of urinary incontinence as for disabled individuals like para- or tetraplegics who frequently have no control permitting voluntary urination.

For such users intermittent catheterization have become increasingly common also in daily life situations outside the clinical environment of a hospital, whereby a significantly improved quality of life has been obtained for this group of patients.

For many such users it is necessary, however, to connect the catheter with a urine collection bag through a hose connected in one end with the bag and in



the other end with the proximal terminal member of the catheter with the inherent disadvantage that several connecting operations must be performed prior to use of the catheter.

5 To overcome this problem it is known e.g. from GB-A-2284764, US-A-2856932, US-A-4379506, US-A-4204527, WO 94/06377, WO 97/26937 and Danish Design Registration No. 0932-1986 to integrate the catheter with the urine collection bag, typically by arranging the catheter  
10 inside the bag combined with a bag design permitting partly withdrawal of the catheter from the bag to provide a projecting catheter of a length sufficient for insertion through the urethra into the bladder.

Whereas catheter-bag combinations of this kind  
15 have undoubtedly facilitated the use of intermittent catheterization it has not remedied the disadvantage associated with disposal of the collected urine.

In a disposable male urethral catheter assembly known from US-A-4,246,909 the catheter-bag combination  
20 is made into a single integrated unit which is disposable after use. A catheter having an enlarged or bulbous discharge end is contained in a sterile environment in an upper chamber of a flexible bag. The upper chamber is detachably connected in one end with  
25 a lower sample chamber for collection of a urine sample and is partly defined in the opposite end by two chevrons defining an opening which is reduced in size relative to the enlarged discharge end of the catheter.

In use the penis is inserted into an open top of  
30 the bag outside the two chevrons and by manipulation of the upper chamber without touching the catheter the latter may be inserted into the urethra, until the enlarged discharge end contacts the opening defined by the two chevrons, whereby the upper chamber forming a  
35 short extension in flow communication with the catheter



will direct a urine sample flowing through the catheter to the lower sample chamber.

This disposable solution suffers, however, from significant cost disadvantages.

5 On this background it is the object of the invention to provide a simple and relatively inexpensive catheter set permitting disabled users even when wheel chair bound to drain the urine flow through the catheter directly into a toilet or other available drainage  
10 means, leaving only the catheter and its package as items which must be disposed after use.

To achieve this object a urinary catheter assembly according to the invention is characterized in that the package includes an intermediate section of a length  
15 which is substantially increased with respect to said predetermined length and distal and proximal end parts, both of which are separable from said intermediate section by local opening means permitting opening of the package, a relatively narrow gateway being defined  
20 by opposed local sections of said package at said distal end part to allow passage of said shaft, but forming a liquid seal against said terminal member when engaged thereby, thereby permitting use of said intermediate section as an extension of said catheter.

25 By this design the part of the catheter shaft needed for introduction through the urethra into the bladder can be retracted from the opening provided by removal of the distal end part of the package while maintaining a sealed connection between the proximal  
30 terminal member and the narrow gateway of the package. The intermediate section of the package will thereby form an extension of the catheter of sufficient length for permitting urine flowing through the catheter from a wheel chair bound user to be drained into the toilet  
35 without any risk of contamination of the users cloth-



ing.

In a preferred embodiment of the invention the assembly comprises a catheter of the kind provided along the part of said shaft intended for introduction  
5 into the urethra with a hydrophilic surface coating requiring wetting by a liquid swelling medium prior to use of the catheter. For this combination a ready to use catheter set can be provided in that the package includes a closed reservoir of said liquid swelling  
10 medium.

Such a reservoir, which may comprise a sachet, pouch or ampoule with manually releasable opening means, may be confined e.g. in said proximal end part of the catheter and be openable by manual operation to  
15 release said liquid swelling medium into said pocket like cavity without opening the package itself.

Alternatively, such a reservoir may be formed as a sachet or pouch of a length sufficient to accommodate the insertable length of the catheter shaft and be  
20 integrally connected with the distal end part of the catheter in extension thereof, the releasable opening means being provided by a easily openable seam permitting the catheter to be pushed into the sachet or pouch which thereby serves as a wetting receptacle or  
25 pocket for the catheter. After the wetting procedure the sachet or pouch is removed together with the distal end part of the catheter thereby exposing a prepared low friction catheter shaft ready for immediate insertion into the urethra.

30 The invention further relates to a method for preparation of a urinary catheter of the kind set forth which is characterized by the steps of manual separation of said distal and proximal end parts from the intermediate section of the package and forwarding the  
35 shaft of the catheter through said narrow gateway to



project from the distal end of the package to a position in which said terminal member engages said gateway for insertion into the urethra, whereas by the separation of said proximal end part a urine outlet is provided at the opposite end of said intermediate section, said intermediate section forming thereby an extension of the catheter to pass urine flowing therethrough to available drain or collection means.

For a catheter assembly including a hydrophilic urinary catheter of the above kind this method may further comprise the steps that prior to said separation a wetting operation is performed by use of said reservoir to prepare the insertable length of the catheter shaft with said liquid swelling medium, and that after a period sufficient for said wetting the reservoir is separated from the package.

In the following the invention will be further explained with reference to the accompanying drawings in which

Figs. 1 to 3 illustrates an embodiment of a urinary catheter assembly according to the invention in the supply condition, during wetting of the catheter surface and with the catheter retracted from the package for insertion into the urethra, respectively;

Fig. 4 is an enlarged representation of a part of the assembly as illustrated in Fig. 3; and

Figs. 5 and 6 are views similar to Figs. 1 and 2 of an alternative embodiment.

In the embodiment shown in Figs. 1 to 4 the urinary catheter assembly intended for intermittent catheterization comprises an elongate urinary catheter 1 of a predetermined length accommodated in an elongate catheter package 2.

The catheter 1 comprises a relatively narrow shaft 3 with a pointed distal end part 4 for insertion into



the urethra and in which urine inlet openings 5 are provided (most clearly seen in Fig. 4), and proximal end part formed by a terminal member 6 having throughout larger cross-sectional dimensions than the shaft 3. In the embodiment shown, the terminal member 6 is funnel-like but could have any suitable shape, eg. cylindrical.

In the embodiment shown, the package 2 comprises walls of a flexible foil material which are formed by two film members which are welded together along the contour of the package in a welding seam 7. The film members may be formed by any suitable material, such as plastic, polymeric materials, cardboard or paper, which may be coated with eg. a metal coating. The welding seam 7 is composed of substantially parallel seam sections extending from a proximal end part 2a of the package via an intermediate section 2b towards a distal end part 2c of the package 2. At the distal end part 2c, which is situated approximately opposite the distal end part 4 of the catheter in the position shown in Fig. 1, a relatively narrow gateway 2d is provided between opposed local sections of the film members forming the walls of the catheter package 2. The intermediate section 2b of the package 2 is substantially longer than both the proximal and distal end part 2a, 2c and the predetermined length of the catheter 1 itself.

At the gateway 2d notch-like incisions 8 and 9 extending through part of the width of the welding seam 7 is provided at either side of the package 2. The incisions 8 and 9 are defined between side flanges 10, 11 and 12, 13, respectively, which are formed by projecting parts of the film members and are joined by external welding seams, and constitute opening means in the form of weakened portions for tearing-up the walls



of the package 2 as will be described in the following.

Corresponding opening means are provided at the opposite, proximal end part 2a in the form of notches 14, 15 extending through part of the welding seam 7 between projecting side flanges 16, 17 and 18, 19.

Although not shown in the drawings, the package 2 could at least partially be designed as a tube member such as a hose of rubber or other more or less flexible material or as a stiffer tube of plastic or other suitable material, in which case the opening means are designed accordingly in order to provide easy opening of the package. In order to facilitate handling of the catheter assembly during catherization, the intermediate section 2b may advantageously be formed as a tube member made from a material having a larger stiffness than the remaining sections of the package.

The part of the catheter shaft 3 which is intended for introduction into the urethra is provided with a hydrophilic surface coating of a kind known *per se*, which by preparation with a liquid swelling medium prior to use of the catheter obtains an extreme low friction in order to enable the catheter shaft 3 to slide very easily through the urethra without exposing the urethral walls to any risk of damage. To this end, a closed reservoir containing liquid swelling medium for activating the low friction surface character of the hydrophilic surface coating in the form of an ampoule 20 is in the embodiment shown provided at the proximal end part 2a of the catheter package 2.

Prior to the intended use of the catheter 1, the ampoule 20 is opened in a manner known *per se*, eg. by twisting the tip of the ampoule, and the liquid swelling medium contained in the ampoule 20 is allowed to flow into the pocket-like cavity accommodating the catheter 1 itself, whereby the position shown in Fig.



2 is attained. After the period needed for preparation of the hydrophilic surface coating (typically about 30 seconds), the distal end part 2c of the catheter package is separated from the intermediate section 2b by tearing-off the distal end part 2c by means of the opening means 8-13.

The catheter 1 may now be withdrawn from the package 2 through the opening formed at the gateway 2d between the constricted sections of the film members to such an extent that the terminal member 6 reaches the opening. Due to the larger cross-sectional dimensions of this member, a liquid seal is achieved in the gateway 2d.

The shaft 3 may now be inserted into the urethral until the distal end part 4 reaches the bladder. In this position, the proximal end part 2a of the catheter package 2 is separated from the intermediate section 2b at the incisions 14, 15. Urine contained in the bladder may now enter through the inlet openings 5 and will subsequently flow through the catheter, via the intermediate section 2b which thereby forms an extension of the catheter, and through an outlet provided by the separation of the proximal end part 2a to be drained into a toilet or other external collecting means.

Following catheterization, the catheter assembly may be disposed of in its entirety.

In order to allow for alternative connection of the catheter to a traditional urine collecting bag via a hose, the catheter package 2 may as shown be provided with further opening means 21, 22 along the intermediate section 2b.

In the following an alternative embodiment will be described with reference to Figs. 5 and 6. Elements having the same or analogous function bear the same reference numerals as in the embodiment described in



the afore-going.

The closed reservoir containing the liquid swelling medium is in this embodiment designed as a sachet 25 which is integrally connected with the distal end part 2c of the catheter package 2 in extension thereof. The sachet 25 has a length substantially corresponding to the length of the catheter shaft 3 or is at least sufficient long so as to accommodate the insertable length of the shaft.

10 In the position shown in Fig. 5, the sachet 25 is closed by a seam 26 which in this embodiment is a peel-off welding seam but may be designed as any suitable kind of easily openable seam. In order to prepare the catheter assembly for use, the catheter shaft 3 is  
15 pushed through the gateway 2d between the narrowed sections of the film members and into the sachet 25 which thereby serves as a wetting receptacle. After the time period required for activating the low friction surface character of the catheter, the sachet 25 is  
20 separated from the intermediate section 2b of the catheter package 2 at the incisions 8, 9. Following this operation, the catheter shaft 3 is inserted into the urethra and the proximal end part 2a of the package is separated from the intermediate section 2b, and  
25 catheterization may take place as described in the above.

Whereas different embodiments of a urinary catheter assembly according to the invention have been described in the above, the invention is not limited to the specific characteristics of these embodiments but  
30 will include numerous modifications without departing from the scope of the following claims.



## P A T E N T   C L A I M S

1. A urinary catheter assembly comprising an elongate urinary catheter (1) of a predetermined length and having a relatively narrow shaft (3) with a pointed distal end part (4) with one or more urine inlet openings (5) for introduction into the urethra and arrangement of said distal end part within the bladder and a proximal end part formed by a terminal member (6) of larger cross-sectional dimensions than said shaft, and an elongate catheter package (2) defining a cavity for relatively narrow accommodation of said shaft, characterized in that the package includes an intermediate section (2b) of a length which is substantially increased with respect to said predetermined length and distal and proximal end parts (2a, 2c), both of which are separable from said intermediate section (2b) by local opening means (8,9; 14,15) permitting opening of the package, a relatively narrow gateway (2d) being defined by opposed local sections of said package at said distal end part (2a) to allow passage of said shaft (3), but forming a liquid seal against said terminal member (6) when engaged thereby, thereby permitting use of said intermediate section (2b) as an extension of said catheter.

25      2. A urinary catheter assembly as claimed in claim 1, characterized in that said package comprises walls of a flexible foil material, and that said opening means permit tearing-up of said walls.

30      3. A urinary catheter assembly as claimed in claim 2, characterized in that said walls comprise two film members welded together along a welding seam (7), that said welding seam is composed of substantially parallel seam sections extending along longitudinal side edges of said film members during said distal and proximal end parts (2c,2a) and said



intermediate section (2b) of the package, said opening means being provided by opposed notch-like incisions (8,9; 14,15) through part of the width of the welding seam.

5        4. A urinary catheter assembly as claimed in claim 3, c h a r a c t e r i z e d in that each of said notch-like incisions (8,9; 14,15) is defined between projecting side flanges (10-13; 16-19) of said film  
10 flanges being joined by an external welding seam.

5. A urinary catheter assembly as claimed in any of claims 1 to 4, c h a r a c t e r i z e d in that said package comprises a tube member.

6. A urinary catheter assembly as claimed in any  
15 of claims 1 to 5, c h a r a c t e r i z e d in that further opening means (21,22) are provided at at least one further location along said intermediate section (2b) between said distal and proximal end parts of the package.

20        7. A urinary catheter assembly as claimed in any of claims 1 to 6, wherein said catheter is of the kind provided along the part of said shaft (3) intended for introduction into the urethra with a hydrophilic surface coating requiring wetting by a liquid swelling  
25 medium prior to use of the catheter, c h a r a c t e r i z e d in that the package (2) includes a closed reservoir (20; 25) of said liquid swelling medium.

8. A urinary catheter assembly as claimed in claim  
30 7, c h a r a c t e r i z e d in that said reservoir comprises a sachet, pouch or ampoule with manually releasable opening means.

9. A urinary catheter assembly as claimed in claim  
8, c h a r a c t e r i z e d in that said reservoir  
35 (20) is confined in said proximal end part (2a) of the



catheter and is openable by manual operation to release said liquid swelling medium into said pocket-like cavity without opening the package itself.

10. A urinary catheter assembly as claimed in  
5 claim 8, c h a r a c t e r i z e d in that said reservoir is formed as a sachet or pouch (25) of a length sufficient to accommodate the insertable length of the catheter shaft and is integrally connected with the distal end part (2c) of the catheter package in  
10 extension thereof, said releasable opening means being provided by an easily openable seam (26) permitting the catheter (1) to be pushed into said reservoir which thereby serves as a wetting receptacle or pocket for the catheter.

15 11. A urinary catheter assembly as claimed in claim 10, c h a r a c t e r i z e d in that said easily openable seam is a peel-off welding seam (26).

12. A method of preparation of the urinary catheter of the catheter assembly claimed in any of claims  
20 1 to 11, c h a r a c t e r i z e d by the steps of manual separation of said distal and proximal end parts (2c,2a) from the intermediate section (2b) of the package (2) and forwarding the shaft (3) of the catheter (1) through said narrow gateway (2d) to project  
25 from the distal end of the package to a position in which said terminal member (6) engages said gateway for insertion into the urethra, whereas by the separation of said proximal end part a urine outlet is provided at the opposite end of said intermediate section, said  
30 intermediate section forming thereby an extension of the catheter to pass urine flowing therethrough to available drain or collection means.

13. A method as claimed in claim 12 for preparation of the catheter of a urine catheter assembly as  
35 claimed in any of claims 8 to 11, c h a r a c t e r -



i z e d in that prior to said separation a wetting operation is performed by use of said reservoir (20; 25) to prepare the insertable length of the catheter shaft with said liquid swelling medium, and that after 5 a period sufficient for said wetting the reservoir is separated from the package.

14. A method as claimed in claim 12 for preparation of the catheter of a urine catheter assembly as claimed in any of claims 10 or 11, c h a r a c t e r -  
10 i z e d in that after operation of said releasable opening means (26) the insertable length of the catheter shaft (3) is pushed through said gateway (2d) into said reservoir (25) which thereby serves as a wetting receptacle or pocket for the catheter, said reservoir  
15 being subsequently separated from the package together with the distal end part thereof to expose a prepared low friction catheter shaft ready for immediate insertion in the urethra.



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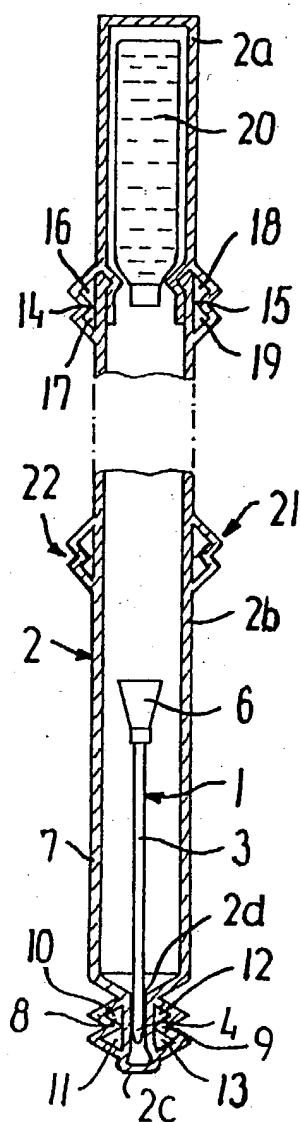


FIG. 1

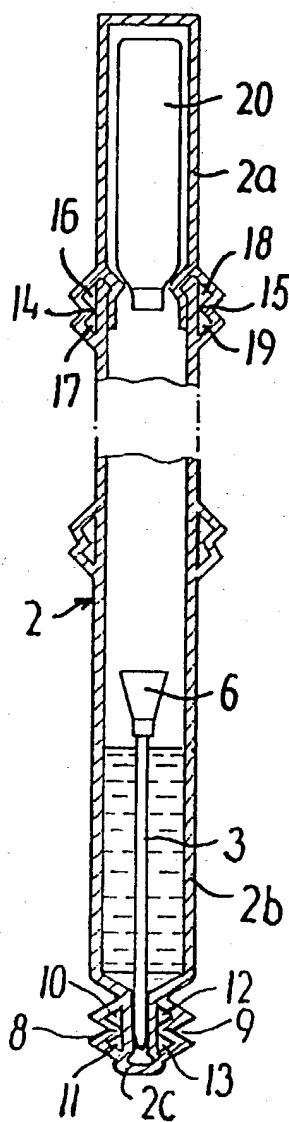


FIG. 2

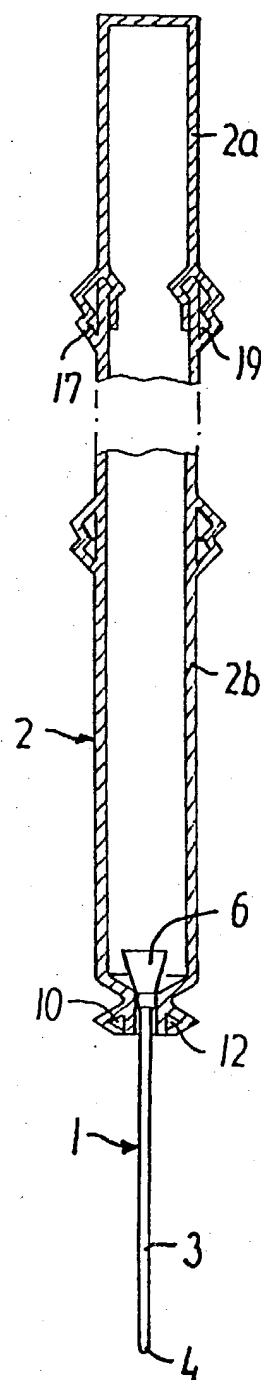


FIG. 3

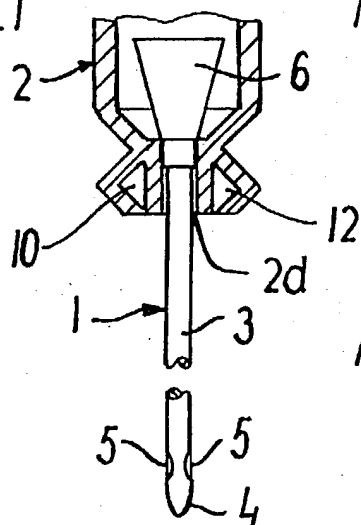


FIG. 4



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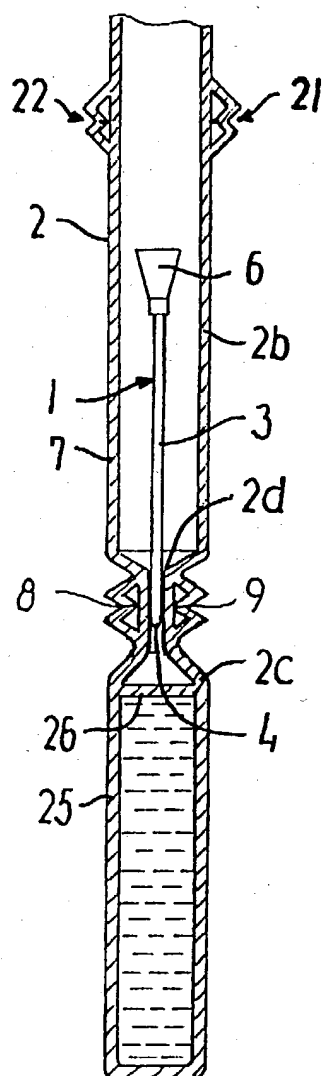
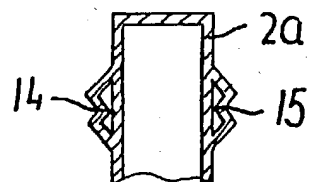


FIG. 5

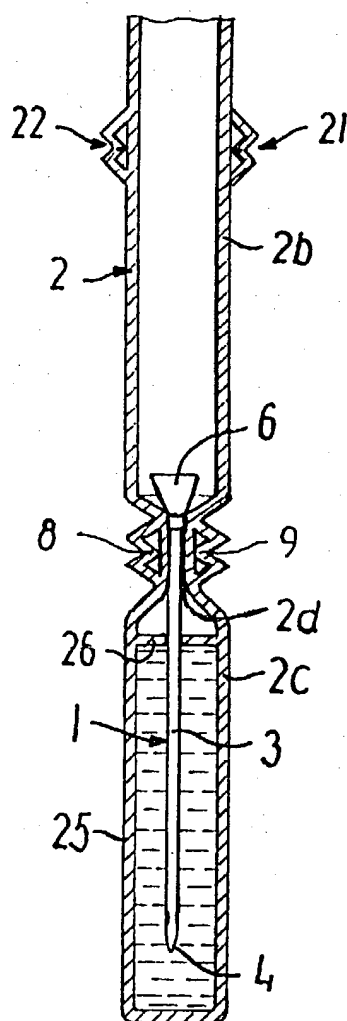
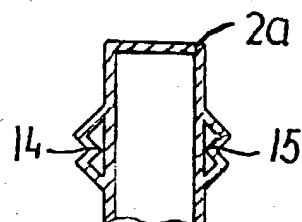


FIG. 6